

K120109

MAR - 7 2012

### 510(k) Summary

**Date:** 1/12/12

**Submission:** Traditional Premarket Notification 510(k) Submission (21CFR 807.90(e)) for a new OTC medical device.

**Company:** Phoenix Dental, Inc.

**Contact:** Jeffrey S. Cox, President/CEO  
**Address:** 3452 West Thompson Rd.  
**City, State, Zip:** Fenton, MI 48430  
**Phone:** (810)750-2328  
**Fax:** (810)750-7495  
**Email:** [jeffreycox@phoenixdental.com](mailto:jeffreycox@phoenixdental.com)

**Trade Name:** Super Seal® Tooth Desensitizer  
**Common Name:** Tooth Desensitizer  
**Panel:** Dental  
**Device Class:** Class II  
**Product Code:** LBH  
**Classification:** Varnish, Cavity

**Substantially Equivalent:** Protect Tooth Desensitizer  
LBH, Varnish, Cavity  
K050486

Orajel Advanced Tooth Desensitizer  
KLE, Agent, Tooth Bonding, Resin  
K041680

**Device Description:** Super Seal ® Tooth Desensitizer is applied with an applicator by the user to aid in dentinal sensitivity. It contains an organic salt that reacts with the calcium hydroxyapatite in the dentinal tubules. The formation of these calcium oxalate crystals inhibits and blocks fluid flow in the tubules, thereby relieving dentinal sensitivity.

**Intended Use:** Single application to aid in the relief from tooth sensitivity.

**Indications for Use:** To aid in the relief from dentinal sensitivity caused by cold, heat, acids, sweets, or as the result from dental whitening agents.

K120109

**Technological Characteristics:** Super Seal® Tooth Desensitizer as well as both predicates occlude the dentinal tubules blocking fluid flow of the dentinal complex. However, Super Seal® Tooth Desensitizer technology differs from the predicates because they place a layer that covers the tooth's surface occluding the tubules; while Super Seal® Tooth Desensitizer reacts with the calcium hydroxyapatite of the surface and peritubular dentin to form calcium oxalate crystals occluding the tubules.

**Performance Data:** The in-vitro Kolker et al. study evaluated the effect on permeability, hydraulic conductance and morphological tubule change. Kolker et al. showed a reduction in dentin permeability and a conical occlusion of the tubules for Super Seal®. A follow up study was performed by Suzaki et al. confirming tubule occlusion. Duran et al. study showed a decrease in permeability by tubule occlusion for HEMA based products.

Suzaki et al., in-vivo portion of their study evaluated 100 cases of human sensitivity and showed Super Seal® was effective to stop patient hypersensitivity. No adverse effects or safety issues pertaining to Super Seal® were found in any of the studies.

**Conclusion:**

From the nonclinical and clinical tests that were performed we conclude that Super Seal® Tooth Desensitizer is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Jeffrey S. Cox  
President / CEO  
Phoenix Dental, Inc.  
3452 West Thompson Road  
Fenton, Michigan 48430

MAR - 7 2012

Re: K120109  
Trade/Device Name: Super Seal<sup>®</sup> Tooth Desensitizer  
Regulation Number: 21 CFR 872.3260  
Regulation Name: Cavity Varnish  
Regulatory Class: II  
Product Code: LBH  
Dated: February 14, 2012  
Received: February 15, 2012

Dear Mr. Cox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Anthony D. Watson'.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K120109

## Indications for Use

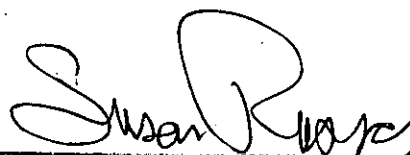
510(k) Number: K120109

Device Name: Super Seal® Tooth Desensitizer

### Indications for Use of Super Seal® Tooth Desensitizer

- To aid in the relief from dentinal sensitivity
- This could be caused by:
  - Cold
  - Heat
  - Acids
  - Sweets
  - Result from dental whitening agents

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use   X    
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K120109